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PTO/SB/21 (03-03)

Approved for use through 04/30/2003. OMB 0651-0031
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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/619,662
	Filing Date	July 15, 2003
	First Named Inventor	William Howard Roark
	Art Unit	1614
	Examiner Name	Unknown
Total Number of Pages in This Submission	Attorney Docket Number	PC25132A

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to a Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	All Required Cited Art
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	Return Postcard
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<input type="checkbox"/> Response to Missing Parts/Incomplete Application	Remarks	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	AUTHORIZATION TO CHARGE THE FEE AND ANY ADDITIONAL FEES AS NECESSARY OR CREDIT ANY OVERPAYMENT TO DEPOSIT ACCOUNT 23-0455 IS HEREBY GIVEN.	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Claude F. Purchase, Jr.
Signature	<i>Claude F. Purchase, Jr.</i>
Date	April 2, 2004

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450 on this date <u>April 2, 2004</u>		
Typed or printed	Nancy Dernbach	
Signature	<i>Nancy Dernbach</i>	Date <u>April 2, 2004</u>

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THE UNITED STATES PATENT AND TRADEMARK OFFICE IS IN RECEIPT OF
AN INFORMATION DISCLOSURE STATEMENT, INCLUDING:

1. TRANSMITTAL FORM (1 PAGE)
2. INFORMATION DISCLOSURE STATEMENT (FORMS PTO/SB/08A AND
PTO/SB/08B (19 PAGES)
3. COPIES OF ALL REQUIRED CITED ART
4. AUTHORIZATION TO DEBIT/CREDIT DEPOSIT ACCOUNT 23-0455
5. CERTIFICATE OF MAILING
6. RETURN POSTCARD

Inventor: W. H. Roark

Invention Titled: "Combination of an Allosteric Carboxylic Inhibitor of Matrix
Metalloproteinase-13 With a Selective Inhibitor of Cyclooxygenase-2 That is Not
Celecoxib or Valdecoxib"

USSN: 10/619,662 FILED: 07/15/2003

CFP:VG/NDD
PC25132A

April 2, 2004



PTO/SB/08A (08-03)

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1

of 19

Complete if Known

Application Number	10/619,662
Filing Date	July 15, 2003
First Named Inventor	William Howard Roark
Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	PC25132A

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 5,082,838	01/21/1992	Naka, et al	
		US- 5,817,819	10/06/1998	Furuya, et al	
		US- 5,948,780	09/07/1999	Peterson Jr., et al	
		US- 6,008,243	12/28/1999	Bender, et al	
		US- 5,747,486	05/05/1998	Sohda, et al	
		US- 5,403,843	04/04/1995	Akimoto, et al	
		US- 5,284,661	02/08/1994	Morimoto, et al	
		US- 5,521,181	05/28/1996	Meyer, et al	
		US- 6,166,019	12/26/2000	Meyer, et al	
		US- 5,334,596	08/02/1994	Hartman, et al	
		US- 4,835,157	05/30/1989	Press, et al	
		US- 5,792,767	08/11/1998	Meyer, et al	
		US- 5,378,704	01/03/1995	Weller III	
		US- 3,296,070	01/03/1967	Topliss, et al	
		US- 2002-0156061	10/24/2002	Barvian, et al	
		US- 2003-0004172	01/02/2003	Harter, et al	
		US- 2002-019377	02/14/2002	Jenkins, et al	
		US- 2002-0151558	10/17/2002	Andrianjara, et al	
		US- 2002-0156069	10/24/2002	Picard, et al	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ ~Number ⁴ ~Kind Code ⁵ (if known)				
		WO 95/35296	12/28/1995	Takatani, et al		
		WO 99/09485	02/24/2000	McClure, et al		
		WO 02/34726	05/02/2001	Noe, et al		
		WO 01/12611	02/22/2001	Blagg		
		WO 02/34753	05/02/2002	Bronk, et al		
		WO 01/05389	01/25/2001	Stallings, et a		

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Sheet	2	of	19
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		• WO 99/05148	02/04/1999	Collins, et al		
		• WO 03/049738	06/19/2003	Weithmann, et al		
		• WO 02/064568	08/22/2002	Barvian, et al		
		• WO 02/064571	08/22/2002	Barvian, et al		
		• WO 01/63244 A1	08/30/2001	Chen, et al		
		• WO 97/07119	02/27/1997	Furuya, et al		

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Sheet	3	of	19
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
		WO 98/54116	12/03/1998	Castelhano, et al		
		WO 96/22991	08/01/1996	Meyer, et al		
		WO 95/28405	10/26/1995	Furuya, et al		
		WO 92/20687	11/26/1992	Chakravarty, et al		
		WO 00/61583	10/19/2000	Klein, et al		
		WO 00/04027	01/27/2000	Meyer, et al		

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		WO 98/49899	11/12/1998	Atherall, et al		
		WO 99/64400	12/16/1999	Salituro, et al		
		WO 97/43239	11/20/1997	Van Zandt, et al		
		WO 02/064080	08/22/2002	Andrianjara, et al		
		WO 02/064572	08/22/2002	Andrianjara, et al		
		WO 00/66584	11/09/2000	Gaudilliere, et al		

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		• WO 97/49692 A	12/31/1997	Pirotte, et al		
		• WO 98/49146	11/05/1998	Kelley, et al		
		• WO 92/20676	11/26/1992	Ito, et al.		
		• EP 0 404 525 B1	05/15/1996	Naka, et al		
		EP 404 525 A	12/27/1990	Naka, et al		

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	6	EP 0935963	08/18/1999	McClure, et al		
	1	EP 1138680	10/04/2001	Noe		
	9	EP 0418797	03/27/1991	Baader, et al		
	✓	EP 0463592	01/02/1992	Baader, et al		
	4	EP 0 915 093 A	05/12/1999	Okamura, et al		
		EP 0 530 537 B1	01/08/1997	Akimoto, et al		

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	✓	EP 0 443 568 A1	08/28/1991	Morimoto, et al		
	✓	EP 0 443 568 B1	06/12/1996	Morimoto, et al		
	/	EP 0 492 316 A1	07/01/1992	Akimoto, et al		
	/	EP 0 502 725 A2	09/09/1992	de Laszlo		
	/	EP 0 530 537 A1	03/10/1993	Akimoto, et al		
	*	EP 0 416 740 A2	03/13/1991	Smith, et al		

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Substitute for form 1449/PTO <div style="text-align: center; font-weight: bold; font-size: 1.2em;"> INFORMATION DISCLOSURE STATEMENT BY APPLICANT </div> <div style="text-align: center; font-style: italic; font-size: 0.8em;"> (Use as many sheets as necessary) </div>		<div style="text-align: center; font-weight: bold; font-size: 1.1em;"> Complete if Known </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/619,662</td> </tr> <tr> <td>Filing Date</td> <td>July 15, 2003</td> </tr> <tr> <td>First Named Inventor</td> <td>William Howard Roark</td> </tr> <tr> <td>Art Unit</td> <td>1614</td> </tr> <tr> <td>Examiner Name</td> <td>Unknown</td> </tr> <tr> <td>Attorney Docket Number</td> <td>PC25132A</td> </tr> </table>		Application Number	10/619,662	Filing Date	July 15, 2003	First Named Inventor	William Howard Roark	Art Unit	1614	Examiner Name	Unknown	Attorney Docket Number	PC25132A
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	-	EP 0 297 661 B1	09/16/1992	Janssens, et al		
	'	EP 0 438 261 A2	07/24/1991	Akimoto, et al		
	'	EP 0 297 661 A1	01/04/1989	Janssens, et al		
	'	EP 0 282 133 B1	09/14/1988	Janssens, et al		
	'	EP 260 057 A2	03/16/1988	Schmalzl, et al		
		EP 0 463 592	01/02/1992	Baader, et al		

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		Art Unit	1614
		Examiner Name	Unknown
Sheet 12 of 19	Attorney Docket Number	PC25132A	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Montana, et al, "The design of selective non-substrate-based matrix metalloproteinase inhibitors", Current Opinion in Drug Discovery & Development, 2000; 3(4); pp 353-261	
		Clark, et al, "Matrix metalloproteinase inhibitors in the treatment of arthritis", Current Opinion in Drug Discovery & Development, 2000; 2(1); pp 16-25	
		Chen, et al, "Structure-Based Design of a Novel, Potent, and Selective Inhibitor for MMP-13 Utilizing NMR Spectroscopy and Computer-Aided Molecular Design", J. Am. Chem. Soc., 2000, 122; pp 9648-9654	
		Derwent Abstract 96-068630/07, "New fused imidazole cpds. - possess inhibitory activity of adhesion molecule expression (Eng.)"	
		Derwent Abstract 93-168431/21, "New Thiazolo-pyrimidine disone derivs. for treating arteriosclerosis"	
		Derwent Abstract 91-001547/01, "New sulphur-Contg. fused pyrimidine cpds. - are endothelin and interleukin inhibitors for treatment and prevention of myocardial infarction, auto:immune diseases,etc.",	
		Derwent Abstract, 93271 E/44, "Cyclised pro-form of 5-fluoro-uracil derivs. - are orally administered antitumour agents without side effects of parent"	
		Kaul, et al, "2-14C-1-Allyl-3,5-diethyl-6-chlorouracil II: Isolation and Structures of the Major Sulfur-Free and Three Minor Sulfur-Containing Metabolites and Mechanism of Biotransformation", Journal of Pharmaceutical Sciences, Vol. 71, No. 8, August 1982; pp 897-900	
		Kaul, et al, "Structure of a novel sulphur-containing metabolite of Acluracil (1-allyl-3,5-diethyl-6-chlorouracil)", Xenobiotica, 1982, Vol. 12, No. 8; pp 495-498	
		Kaul, et al, "Identifizierung eines dritten S-haltigen Metaboliten von 1-Allyl-3,4-diethyl-6-chloruracil und Bildungsmechanismus der SCH - Metaboliten", Arzneim.-Forsch./Drug Res., 1982; 32(I)(6); pp 610-612	

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		Brown, et al, "The Synthesis of Some 1-Substituted Cytosine and Uracil Derivatives", J. Chem. Soc., 1972; pp 2385-2391	
		Pecorari, et al, "Synthesis and Biological activity of Pyrimido [2,1-b] [1,3] Thiazine, [1,3]Thiazino[3,2-a]Purine and [1,2,3]Triazolo[4,5-d][1,3]Thiazine [3,2-a]Pyrimidine Derivatives and thiazole Analogues (*)", IL Farmaco, 46 (7,8), 1991; pp 899-911	
		De Melo, et al, "5-fluoro (3H) pyrimidine-4-ones; syntehse, reactivite et proprietes pharmacologiques", Ann. Pharmaceutiques francaises, 1992, 50, n1; pp 39-51	
		Faskhutdinow, et al, Kim. Farm. Zh. 1988; 22(5); pp 557	
		Tozkoparan, et al, "Condensed Heterocyclic Compounds: Synthesis and Antiinflammatory Activity of Novel Thiazolo[3,2-a]pyrimidines", Arch. Pharm. Pharm. Med. Chem. 331 (Weinheim, Germany): 1998; pp 201-206	
		Chem. Abstr. 1992; 117; pp 143023e	
		Chem. Abstr. 1988; 109; pp 162901r	
		Boger, et al, "Identification of a novel class of small-molecule antiangiogenic agents through the screening of combinatorial libraries which function by inhibiting the binding and localization of proteinase MMP2 to integrin. alpha. V. beta 3", Journal of the American Chemical Society 2001; 123; pp 1280-1288	
		Silletti, et al, "Disruption of matrix metalloproteinase 2 binding to integrin alpha v beta 3 by an organic molecule inhibits angiogenesis and tumor growth in vivo", Proceeding of the National Academy of Sciences of the United States of America, 2001; 98(1); pp 119-124	
		Milton, et al, "Biaryl acids: novel non-nucleoside inhibitors of HIV reverse transcriptase types 1 and 2", Bioorganic & Medicinal Chemistry Letters, Oxford, GB 1998; 8: pp 2623-2628	

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		Hirota, et al, "Synthesis of 6-Substituted Thieno[2,3-d]pyrimidine-2,4(1H,3H)-diones", J. Heterocycl. Chem., Vol 12, 1974; pp 717-721	
		Rajappa, et al, "Synthesis of Thiophenes: Part III* - Further Variations in the Substitution Pattern", Indian J. Chem., Vol 12, 1974; pp 1-3	
		HCAPLUS Abstract 1998: 542760; "Preparation of bicyclic-substituted hexahydrobenz [e] isoindoles as a1 adrenergic antagonists"	
		HCAPLUS Abstract 1990: 514925; "Pyrimidines. 65. Synthesis of 6-substituted thieno [2,3-d] pyrimidine-2 4(1H,3H) - diones"	
		Derwent Abstract 2000-687031/67, "New Xanthine derivatives are inhibitors of cellular processes mediated by interleukin-12 for treating inflammatory responses e.g. chronic inflammatory disease, chronic intestinal inflammation, arthritis, psoriasis and asthma (Eng)"	
		Derwent Abstract 92-415690/50, "New Pyrimidinone derivs are angiotensin II antagonists for treating hypertension, congestive heart failure, renal failure, Alzheimer's disease, amnesia, schizophrenia, etc. (Eng)"	
		Derwent Abstract 92-302020/37, "New fused pyrimidinone derivs. - are antitensin II antagonists to treat hypertension, congestive heart failure, Alzheimer's disease, amnesia, anxiety, schizophrenia, etc. (Eng)"	
		Derwent Abstract 91-254180/35, "New angiotensin-II antagonising fused thiphenes derivatives - used for treating hypertension and circulatory diseases including heart diseases and stroke"	
		Derwent Abstract 89-192246/26, "New 3-piperidinyl:alkyl-thieno: or furo pyrimidine-2,4-di:one cpds. - usefule as seratonin antagonists and alpha adrenergic blockers"	
		Derwent Abstract 2000-195023/17, "New ipiperazinyl pyrimidine dione derivatives used as selective alpha-ID adrenoceptor antagonists for treating benign prostatic hyperplasia, hypertension, detrusor instability and incontinence (Eng)"	

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		Derwent Abstract 2001-158207/16, "New piperazinyl pyrimidine dione derivatives are selective alpha-ID adrenoceptor antagonists used for treatment of e.g. hypertension"	
		Derwent Abstract 96-362624/36, "New Bi:cyclic substd. hexa:hydro-benz-isoindeole derivs. - are alpha-1 adrenergic antagonists, used in treatment of benign prostatic hyperplasia (Eng)"	
		Derwent Abstract 89-008928/02, "New bi:cyclic heterocycle substd. hexa-hydro-1H-azepine-and pyrrolidine cpds., have anti-histaminic properties, for treatment of e.g. allergic rhinitis, allergic asthma, etc."	
		Derwent Abstract 88-258874/37, "New 1-alkyl substd. benzimidazole derivs. - having anti-histaminic activity and used for treating allergic diseases such as allergic asthma"	
		Derwent Abstract 91-216939/30, "New condensed heterocyclic glutemic acid dervis., - active against enzyme using folic acid and antitumour agents for treating e.g. leukemia"	
		Derwent Abstract 99-080786/07, "New thiophene-and pyrrole-based hetero-aromatic compounds - are ant(agonists of cell surface receptors, useful e.g. for inhibiting unwanted cell growth e.g. due to cancer (Eng)"	
		Derwent Abstract 97-165234/15, "New thieno-pyrimidine derivs. are endothelin antagonists - useful for treating e.g. acute renal failure, cardiac infarction, liver insufficiency, organ hypo-function and vasoconstriction (Eng)"	
		Derwent Abstract 96-384384/38, "New 2,4(1H,3H)-di:oxo-5-aminoalkyl)thieno(2,3-d)-pyrimidine derivs. - are gonadotropin-releasing hormone antagonistic agents useful in prevention and treatment of sex hormone dependent diseases (Eng)"	
		Derwent Abstract 95-382760/49, "Fused bicyclics as gonadotropin releasing hormone antagonists - used for treating hormone related cancers, benign prostatic hypertrophy, acne vulgaris, etc. (Eng)"	
		Derwent Abstract 93-299636/38, "New condensed heterocyclic oligo-glutamate derivs. - used as water soluble antitumour agent and have bood storage stability in cells"	

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		Derwent Abstract 93-078155/10, "New antitumour condensed pyrimidine derivs. - for treating chorlocarcinoma, leukemia, breast adenocarcinoma, squamous cells carcinoma, lung cancer, lympho sarcoma, etc. and also rheumatism (Eng)"	
		Derwent Abstract 92-218561/27, "Antitumoural condensed heterocyclic oligo:glutamate derivs. - for treating leukemia, squamous cell carcinoma, lymphatic sarcoma, small cell cancer of the lung etc. (Eng)"	
		Derwent Abstract 96-267825/27, "New hexa:hydro benz(e)isoindole cpds. - are useful in treatment of benign prostatic hpyerplasia (Eng)"	
		Derwent Abstract 94-248420/30, "Furano- and thieno- (3,2-c)piperidone carboxamido-acids - are fibrinogen receptor antagonists, inhibit blood platelet aggretation, used in thrombi and emboli treatment"	
		Derwent Abstract 91-075241/11, "Heterocyclic peptide derivs. useful as renin inhibitors - in the treatment of hypertension, congestive heart failure, retro-viral diseases and central nervous system disorders"	
		HCAPLUS Abstract 1996:580284: "Preparation of heterocyclyl-substituted benz[3]isoindoles as x1 adrenergic antagonists"	
		Liverton, et al, "Nonpeptide glycoprotein IIb/IIIa inhibitors: substituted quinazoliniones and quinazolinones as potent fibrinogen receptor antagonists", Bioorganic & Medicinal Chemistry Letters, 1998; 8(5); pp 483-486	
		Ogawa, et al, "Studies on positive inotropic agents V", Chem Pharm Bull, 1988; 36(6); pp 2253-2258	
		Chemical Abstract CHEMCATS: AN 2001: 142935 for Order no. A1240/0056923 "Screening Collection", Zelinsky Institute of Organic Chemistry, Russia, 2000	
		Chemical Abstract CHEMCATS: AN 2001:2519212, 2001:2519208, and 2001:2519206 for Order no.s CHS 1938401, CHS 1938397, and CHS 1938395, respectively, "Chemstar Product List", Chemstar Ltd. Russia, 2001	

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		Chemical Abstract: CHEMCATS: AN 2001:2624610, 2001:2320591, 2002:928648, 2002:925092, 2002:926648, and 2002:927094 for Order nos. STOCKIN-22756, A1336/0060317, STOCKIS-85693, STOCKIS-77305, STOCKIS-81043, and STOCKIS-82046, respectively, "Ambinter:Exploratory Library", Ambinter, Paris, 2002	
		Chemical Abstract CHEMCATS: AN 2001:1621701, 2001:1621700, 2001:1433023, 2001:1433022, and 2001:1433020 for Order nos. Z-007159, Z-007158, C-055659, C-055658, and C-055656, respectively, "Scientific Exchange Product List", Scientific Exchange, Inc., USA, 2001	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/619,662
		Filing Date	July 15, 2003
		First Named Inventor	William Howard Roark
		Art Unit	1614
		Examiner Name	Unknown
Sheet 18	of 19	Attorney Docket Number	PC25132A

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Derwent Abstract 95-051281/07, "New benzo- and pyrido- 1,2,4-thiadiazine dioxide derivs - are angiotension II inhibitors, use in treatment of hypertension and congestive heart failure"	
		Chemical Abstracts, Vol 125, No. 13, 1996, Abstract No. 167964d; XP002198554	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number 10/619,662

Filing Date July 15, 2003

First Named Inventor William Howard Roark

Art Unit 1614

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Attorney Docket Number PC25132A

Sheet 19 of 19

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		Database Crossfire Bulletin, 'Online, Database accession no. 791572; XP002198559	
		Sakasi, et al, "Studies in Pyrimidine Derivatives. XVII. Synthesis of Pyrimidine-4-Carboxyl Heterocycles", 1979; 13; pp 235-236	
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		Chemical Abstracts: AN 55:10440b "Solubilizing agents. V. Pyridinecarboxamides" (XP002202691)	

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